Remarks

Claims 23-40 are pending in the subject application. By this Amendment, Applicants have canceled claims 28-30, 32, 34, 35, and 38, and added new claims 41-46. Support for the new claims and amendments can be found throughout the subject specification and in the claims as originally filed. Applicants have also amended the "Cross-Reference to Related Application" section of the specification to include the patent number of U.S. application No. 10/314,206, which the subject application claims benefit under 35 USC §120. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 23-27, 31, 33, 36, 37, 39-46 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's indication that claims 34 and 35 are objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims. Accordingly Applicants note that claims 34 and 35 have been rewritten as new independent claims 43 and 44.

Claims 23-25, 31-34, and 36-39 are rejected under 35 USC §102(b) as anticipated by Del Mar *et al.* (U.S. Patent No. 6,117,077). The Examiner asserts that the Del Mar *et al.* patent teaches an ambulatory physiological recording device that has a housing **10** provided with several adhesive electrode pads **12**, **14**, and **16**. The Examiner also asserts that the Del Mar *et al.* patent teaches that sensors **30**, **32**, and **34** reside in electrode pads **12**, **14**, and **16**, column 5, lines 26-33, and can be utilized to record any bioelectric potentials, such as ECG, EEG, or EMG, column 7, lines 55-59. Applicants respectfully traverse this ground of rejection.

As an initial matter, Applicants note that claim 34 is included in the rejection; however, as noted above, the Examiner indicates in the Office Action that claim 34 is allowable. Accordingly, Applicants will assume that claim 34 is not included under this rejection.

The Examiner asserts that claims 23 and 39 are anticipated by the Del Mar *et al.* patent. It is submitted that this objection is not correct. The Examiner states that the housing **10** in the Del Mar *et al.* patent is coupled to electrode pads **12**, **14** and **16**, which substantially anticipates the "support means for attaching the monitor device to adhesive electrodes". However, claims 23 and 39 in the subject application clearly recite that the support means of the monitor is for attachment to a single

adhesive ECG electrode. In contrast, the Del Mar *et al.* patent explicitly states, at column 1, line 13, that the solid state recorder is supported on "at least two adhesively attached sensor electrodes" (emphasis added). In fact, all of the monitors illustrated in the Del Mar *et al.* patent are supported on three adhesive electrodes. Applicants respectfully assert that the Del Mar *et al.* patent does not teach or suggest a monitor supported on a single adhesive electrode.

As the Examiner is aware, in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). As can be understood herein, the Del Mar *et al.* patent fails to teach each and every element of Applicants' claimed invention. Thus, the Del Mar *et al.* patent does not anticipate the claims.

Dependent claim 36 is also rejected as anticipated by the Del Mar *et al.* patent. Claim 36 recites that the monitor comprises contacts for making contact with two ECG electrodes (one being the electrode on which the monitor is supported and the other being the electrode to which the monitor is connected by an electrical lead), in which the same contacts are couplable to an interface for various other purposes, including transferring data from and/or to the monitor, re-setting or re-programming the monitor, and/or for re-charging a battery for powering the monitor. It is submitted that the Del Mar *et al.* patent does not teach or suggest the monitor of claim 36 because the only purpose of the ECG contacts in the recorder of the Del Mar *et al.* patent is to make contact with ECG pads for ECG measurements. A completely separate interface is provided by the Del Mar *et al.* patent, as shown in Figures 2 and 6 of the patent in the form of a USB socket, for connecting the recorder to a remote computer for data transfer or battery charging.

It is an important and advantageous feature of the monitor in Applicants' claimed invention that the same contacts are used for ECG monitoring and for other purposes such as data transfer to a remote computer, and for re-charging the monitor's battery. This is because the multi-function use of these contacts advantageously enables the size of the monitor to be reduced, by eliminating the need for a separate interface such as the USB connector utilized in the recorder shown in the Del Mar *et al.* patent.

In regard to the rejection of claim 37 as anticipated by the Del Mar *et al.* patent, Applicants note that claim 37 recites that the monitor in use is secured to the chest or torso of the user so that the

accelerometer (as defined in claim 33) is oriented to sense vertical movements of the user's chest or torso. The Examiner asserts that this claim lacks novelty over the Del Mar *et al.* patent on the grounds that in Del Mar *et al.* "the acceleration transducer could be used to monitor any body movements". However, Applicants respectfully assert that the Del Mar *et al.* patent does not teach or suggest each and every element of claim 37 because the Del Mar *et al.* patent does not specify the sensing of vertical movements of the user's chest or torso. Further, Applicants have found that sensing these vertical movements is particularly effective in monitoring the user's physical movement. In addition, this feature allows a further reduction in the size of the monitor, by requiring only a unidirectional accelerometer. For example, if the acceleration transducer in the Del Mar *et al.* patent could be used to monitor any body movements, then a multi-axial acceleration transducer must be required. By selecting only a single movement direction and simplifying the accelerometer, Applicants can advantageously reduce the size of their monitor, without adversely affecting its performance, and enable it to be supported on a single adhesive pad.

Applicants further note that there are a number of disadvantages in the structure of the monitor in the Del Mar *et al.* patent, which stretches between two or more widely-spaced ECG pads (the pads need to be widely spaced in order to achieve satisfactory ECG sensing). Primarily, the rigidity of the unit would be a significant problem. The Del Mar *et al.* patent mentions, in claim 2, that the housing of the recorder is advantageously "soft, flexible, and compliant to body tissue movement". However, the Del Mar *et al.* patent describes no such soft or flexible structure and it can be seen from Figures 2 and 6 that the recorders in the Del Mar *et al.* patent comprise large circuit boards extending between the adhesive pads. Circuit boards cannot satisfactorily be made flexible and, therefore, it can be understood that the Del Mar *et al.* patent does not teach or suggest a solution to the problem of housing a rigid recorder structure bridging two or more spaced-apart adhesive pads. By contrast, Applicants' invention elegantly solves this problem by supporting a monitor on a single ECG pad and using a flexible lead to connect the monitor to a second ECG pad, as is required for ECG sensing. Thus, the invention allows the use of a rigid monitor casing to house a rigid circuit board, which is easily manufacturable, while avoiding any problems caused by relative movement of the two electrodes. Other advantages of the use of a single ECG pad to support the monitor in Applicants' claimed invention are described in the subject application.

Applicants note that new claim 44 recites that the maximum lateral dimension of the monitor is less than or equal to the maximum lateral dimension of the ECG electrode, on which the monitor is supported. Applicants respectfully asserts that this additional feature further distinguishes over the Del Mar *et al.* patent because, if the lateral dimension of the monitor is less than that of the ECG pad, it is difficult to see that the monitor could be supported on two or more ECG pads (in the manner of Del Mar *et al.*) without the ECG pads overlapping. This circumstance would be unacceptable as the adhesion and/or the electrical performance of the pads may then be adversely affected.

Also submitted with this Amendment is new independent claim 42. New claim 42 recites the feature that the monitor, in use, does not extend beyond an outer edge of the single ECG electrode on which it is supported. This definition clearly differentiates the monitor from the recorder described in the Del Mar *et al.* patent because, if the monitor does not extend beyond an outer edge of the single ECG electrode, it cannot be supported on two or more electrodes as required by Del Mar *et al.* This structure additionally prevents any part of the monitor from contacting skin not protected by the ECG pad. This advantageously reduces any risk of electrical interference, by ensuring that contact with the skin is made only through the ECG contact itself.

A conventional ECG pad comprises a circular contact, for connection to a clip at the end of an ECG lead. The conventional clip is constructed so that the clip can rotate freely on the ECG pad contact. This improves the user's comfort during ECG measurement. However, if the monitor of the invention comprises a uni-axial accelerometer and is intended for sensing vertical movements of the user's chest or torso, it is important that the monitor should not rotate on the single ECG pad to which it is attached. Consequently, the support means for attaching the monitor to the single ECG electrode is such that the monitor will not rotate on the pad during use. This feature is described in the subject application at page 5 and has been included in new claim 41. The feature of claim 41 therefore clearly distinguishes the present invention from the Del Mar *et al.* patent.

In view of the above remarks, reconsideration and withdrawal of the rejection under 35 USC §102(b), is respectfully requested.

Claims 26-30 are rejected under 35 USC §103(a) as obvious over Del Mar *et al.* (U.S. Patent No. 6,117,077). The Examiner asserts that it would have been obvious to an ordinarily skilled

artisan that the invention described by the Del Mar *et al.* patent would perform equally as well as Applicants' claimed invention since the size of the components would not effect the functioning of the device. The Examiner also asserts that the invention of the Del Mar *et al.* patent is constructed of a size that is reasonably comfortable to wear since the Del Mar *et al.* patent suggests that the system can be covertly and comfortably held in place under the clothing. Applicants respectfully traverse this ground of rejection.

As an initial matter, Applicants note that claims 28-30 have been canceled by this Amendment, thereby rendering the rejection of these claims moot. In regard to claims 26 and 27, Applicants respectfully assert that the Del Mar *et al.* patent does not teach or suggest the claimed invention. Applicants hereby incorporate their comments submitted in regard to the §102 rejection in response to this obviousness rejection. As the Examiner is aware, it is well established in patent law that in order to support a *prima facie* case of obviousness, a person of ordinary skill in the art must find both the suggestion of the claimed invention, and a reasonable expectation of success in making that invention, solely in light of the teachings of the prior art. *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). As noted previously, the Del Mar *et al.* patent does not teach or suggest a monitor supported on a single adhesive electrode. The Del Mar *et al.* patent only discloses a recorder supported on multiple electrodes. Accordingly, the Del Mar *et al.* patent does not render claims 26 and 27 obvious. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §103(a), is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Doran R. Pace
Patent Attorney
Registration No. 38,261
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRP/jil/kmm